

**STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY**

IN RE:)	
)	
JAMES M. KEOWN)	
License No. 040289)	Complaint No. 2017-004890
200 Robin Terrace)	
Columbia, MO 65201)	

**SETTLEMENT AGREEMENT BETWEEN
THE MISSOURI BOARD OF PHARMACY AND JAMES M. KEOWN**

Come now James M. Keown (“Respondent” or “Licensee”) and the Missouri Board of Pharmacy (“Board” or “Petitioner”) and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent’s license to practice pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties have waived the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that he understands the various rights and privileges afforded him by law, including the right to a hearing of the charges against him; the right to appear and be represented by counsel; the right to have all charges against him proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against him; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against him and, subsequently, the right to a disciplinary hearing before the Board at which time he may present evidence in mitigation of discipline; and the right to recover attorney’s fees incurred in defending this action against his license. Being aware of these rights provided him by operation of law, Respondent knowingly

and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to him.

Respondent has previously stipulated in Case No. 18-0590 filed with the Missouri Administrative Hearing Commission that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license to practice pharmacy, numbered 040289, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo (2016),¹ for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. James M. Keown is licensed as a pharmacist under the laws of the State of Missouri, License No. 040289. Respondent's license was at all times relevant herein current and active.

3. Respondent is licensed as a pharmacist under the laws of the State of Missouri, License No. 040289. Respondent's license was at all times relevant herein current and active.

4. At all times relevant herein, Respondent was employed as a staff pharmacist at Wal-Mart Pharmacy #10-451 in Columbia, Missouri (the "Pharmacy").

5. On or about August 17, 2017, the Board received an online notice and a facsimile from the Pharmacy that Respondent's employment had been terminated on July 31, 2017 after he admitted to diverting clonazepam and trazodone for personal use and consumption.

¹ All statutory references are to the Revised Statutes of Missouri (2016) unless otherwise indicated.

6. The Pharmacy also filed loss reports with the Missouri Bureau of Narcotics and Dangerous Drugs and the Drug Enforcement Administration indicating a loss of 601 units of clonazepam 2mg.

7. In June 2017, the Pharmacy conducted an audit of controlled substances due to an inventory concern about Oxycodone/APAP 10/325mg.

8. The audit revealed a shortage of 399 clonazepam 2mg.

9. Further investigation revealed a negative adjustment of 100 tablets to the on-hand inventory of clonazepam 2mg on May 16, 2017, under pharmacist-in-charge ("PIC") S.G.'s user name.

10. Security video footage showed Respondent making the adjustment entry on May 16, 2017, while at the PIC's computer terminal.

11. Another negative adjustment of 100 tablets of clonazepam 2mg was made by Respondent under the PIC's user name on July 3, 2017.

12. On July 27, 2017, a 100-count stock bottle of clonazepam 2mg went missing from the shelf.

13. Security video footage showed Respondent removing a stock bottle in the vicinity of clonazepam 2mg from the shelf and eventually placing it in a plastic sack and leaving the building with the sack.

14. On July 31, 2017, Respondent admitted to the Pharmacy to taking four to five bottles of clonazepam and 60-70 trazodone to help him sleep. Respondent's employment was then terminated and he was taken into custody by the Columbia Police Department.

15. Clonazepam is a schedule IV controlled substance and trazodone is a non-controlled substance, but requires a prescription.

16. In total, four negative adjustments in quantities of 100 were made to the clonazepam 2mg inventory under the PIC's username on October 6, 2016, December 20, 2016, Mary 16, 2017 and July 3, 2017.

17. During a September 13, 2017 interview with Board Inspectors, Respondent admitted to taking approximately 430 clonazepam 2mg by removing stock bottles or return-to-stock vials from the shelf and taking them home and adjusting the stock inventory to account for what he took.

18. Respondent intentionally used the PIC's user name to make the adjustments at the PIC's computer terminal when he stepped away to conceal his actions.

19. Respondent had 300 tablets of clonazepam 2mg stockpiled at home when he was terminated.

20. Respondent suffered from lack of sleep due to what he believes to be his position as a floater pharmacist for 20 stores, some of which are far away from his home in Columbia, MO.

21. Respondent's primary care physician prescribed him trazodone and bupropion to help his lack of sleep issue, but he did not believe those medications were successful.

22. Because he had been prescribed clonazepam in 2013 to help him sleep, he started taking it from the Pharmacy without a prescription.

23. During the September 13, 2017, interview with the Board Inspectors, Respondent stated that the written statement he provided to the Pharmacy was accurate.

Unlawful dispensing/possession of controlled substances/stealing

24. Respondent's possession of clonazepam without a valid prescription is in violation of §579.015.1, RSMo² which states:

1. A person commits the offense of possession of a controlled substance if he or she knowingly possesses a controlled substance, except as authorized by this chapter or chapter 195.

25. By taking clonazepam for his personal use from the Pharmacy stock without a valid prescription and adjusting the inventory to prevent detection, Respondent further violated Missouri law, to wit:

1. A person commits the offense of fraudulently attempting to obtain a controlled substance if he or she knowingly obtains or attempts to obtain a controlled substance, or knowingly procures or attempts to procure an administration of the controlled substance by fraud. The offense of fraudulently attempting to obtain a controlled substance shall include, but shall not be limited to nor be limited by, the following:

(1) Knowingly making a false statement in any prescription, order, report, or record, required by this chapter or chapter 195;

(2) For the purpose of obtaining a controlled substance, falsely assuming the title of, or representing oneself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, podiatrist, veterinarian, nurse, or other authorized person;

(3) Making or uttering any false or forged prescription or false or forged written order;

(4) Affixing any false or forged label to a package or receptacle containing controlled substances;

(5) Possess a false or forged prescription with intent to obtain a controlled substance. § 579.045.1, RSMo³

² Prior to January 1, 2017, § 579.015.1, RSMo, was located at § 195.202.1, RSMo. Respondent's actions prior to January 1, 2017 violated § 195.202.1, RSMo which stated:

1. Except as authorized by sections 195.005 to 196.425, it is unlawful for any person to possess or have under his control a controlled substance. . .

³ Section 579.045 was transferred from section 195.204 effective January 1, 2017. Respondent's actions prior to January 1, 2017 violated § 195.204.1, RSMo which stated:

1. A person commits the offense of fraudulently attempting to obtain a controlled substance if he obtains or attempts to obtain a controlled substance or procures or attempts to procure the

26. By taking clonazepam for his personal use from the Pharmacy stock without a valid prescription and adjusting the inventory to prevent detection, Respondent violated §195.060.1, RSMo⁴ which states:

1. Except as provided in subsection 4 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute. . .

27. By taking clonazepam for his personal use from the Pharmacy stock without a valid prescription and adjusting the inventory to prevent detection, Respondent violated 21 U.S.C. § 841(a),⁵ to wit:

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally--

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

28. By taking clonazepam for his personal use from the Pharmacy stock without a valid prescription and adjusting the inventory to prevent detection, Respondent violated 21 U.S.C. § 844(a):

(a) Unlawful acts; penalties

It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter . . .

administration of the controlled substance by fraud, deceit, misrepresentation, or subterfuge; or by the forgery or alteration of a prescription or of any written order; or by the concealment of a material fact; or by the use of a false name or the giving of a false address. . . .

⁴ Section 195.060, RSMo, was amended effective January 1, 2017. However, the relevant language of the statute cited herein was not changed from the earlier version. Respondent's diversion of controlled substances prior to January 1, 2017 was in violation of Section 195.060.1, RSMo as it existed prior to January 1, 2017.

⁵ All statutory references are to the United States Code (2012), as supplemented, unless otherwise indicated.

29. By dispensing a clonazepam, a Schedule IV controlled substance, to himself without a valid prescription, Respondent violated 21 C.F.R. § 1306.21(a), which states:

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

30. Respondent's diversion of clonazepam for his personal use from the Pharmacy stock without a valid prescription and adjusting the inventory to prevent detection also constitutes stealing under Missouri statute, to wit:

1. A person commits the offense of stealing if he or she:

(1) Appropriates property or services of another with the purpose to deprive him or her thereof, either without his or her consent or by means of deceit or coercion;

* * *

5. The offense of stealing is a class D felony if:

(3) The property appropriated consists of:

(m) Any controlled substance as defined by section 195.010; § 570.030, RSMo⁶

⁶ Section 570.030, RSMo was amended effective January 1, 2017. Respondent's actions prior to January 1, 2017 violated the earlier version of § 570.030, RSMo, which stated:

1. A person commits the crime of stealing if he or she appropriates property or services of another with the purpose to deprive him or her thereof, either without his or her consent or by means of deceit or coercion.

* * *

3. Notwithstanding any other provision of law, any offense in which the value of property or services is an element is a class C felony if:

(3) The property appropriated consists of:

Misbranding

31. Section 196.015(1)-(2), RSMo prohibits misbranding of drugs in the State of Missouri, to wit:

The following acts and the causing thereof within the state of Missouri are hereby prohibited:

- (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
- (2) the adulteration or misbranding of any food, drug, device, or cosmetic;

32. Misbranding of a drug under Missouri law is defined in § 196.100.1, RSMo, which states in pertinent part:

1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

33. A drug or device shall be deemed to be misbranded under federal law “[i]f its labeling is false or misleading in any particular.” 21 U.S.C. § 352(a)(1).

34. A legend drug is misbranded under 21 U.S.C. §353(b)(1) of the Federal Food, Drug and Cosmetic Act, as amended, under the following circumstances:

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

- (1) A drug intended for use by man which –
 - (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
 - (B) is limited by an approved application under section 355 of this title to use under

(m) Any controlled substance as defined by section 195.010;

the professional supervision of a practitioner
licensed by law to administer such drug;
shall be dispensed only (i) upon a written prescription of a
practitioner licensed by law to administer such drug, or (ii)
upon an oral prescription of such practitioner which is
reduced promptly to writing and filed by the pharmacist, or
(iii) by refilling any such written prescription if such
refilling is authorized by the prescriber either in the original
prescription or by oral order which is reduced promptly to
writing and filed by the pharmacist. The act of dispensing
a drug contrary to the provisions of this paragraph shall be
deemed to be an act which results in the drug being
misbranded while held for sale.

35. Federal law also prohibits:

- (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.
 - (b) The adulteration or misbranding of any . . . drug . . . in interstate commerce.
- 21 U.S.C. § 331(a)-(b).

36. Respondent's unauthorized dispensing of clonazepam and trazodone to himself constitutes misbranding in violation of §§ 196.100, .015, RSMo, and 21 U.S.C. §§ 331, 352-353.

Inaccurate Records

37. According to 20 CSR § 2220-2.080:

- (1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.
- (2) EDP systems shall comply with the requirements of section 338.100, RSMo, and shall be capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:

- (A) A unique, sequential prescription label number;
- (B) If applicable, a unique readily retrievable identifier;
- (C) Date the prescription was prescribed;
- (D) The date the prescription was initially filled and the date of each refill;
- (E) Patient's full name, or if an animal, the species and owner's name;
- (F) Patient's address or animal owner's address when a prescription prescribes a controlled substance;
- (G) Prescriber's full name;
- (H) Prescriber's address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;
- (I) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
- (J) Quantity originally dispensed;
- (K) Quantity dispensed on each refill;
- (L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
- (M) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;
- (N) The number of authorized refills and quantity remaining;
- (O) Whether generic substitution has been authorized by the prescriber;
- (P) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and
- (Q) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(3) The information specified in section (2) shall be required and recorded in the EDP system prior to dispensing by a pharmacist or pharmacy.

38. Respondent created inaccurate pharmacy records in violation of 20 CSR § 2220-2.080(1)-(3) by dispensing legend drugs to himself without valid prescriptions and making invalid and unauthorized adjustments in the Pharmacy's records under another pharmacist's name.

JOINT CONCLUSIONS OF LAW

39. Respondent's conduct is cause for disciplinary action against his license to practice pharmacy under § 338.055.2(5), (6), (13), (15) and (17), RSMo, which provides:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

* * *

(17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.1, RSMo:

1. Respondent's license to practice pharmacy numbered 040289 shall be **SURRENDERED**, effective upon execution of the attached Affidavit of Voluntary Surrender of License to Practice Pharmacy.

2. That the terms and conditions set forth in the attached Affidavit of Voluntary Surrender of License to Practice Pharmacy shall apply and herein bind Respondent.

3. Respondent agrees not to submit an Application for New Pharmacy License for a period of seven (7) years from the date of the Settlement Agreement herein executed.

4. Respondent shall return all indicia of licensure, i.e., the computer generated 5" x 7" license, and the wallet card, to the Board Office on or before the effective date of this agreement.

5. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

6. No order shall be entered by the Board pursuant to the preceding paragraph of this agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 538, RSMo.

7. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement

Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

8. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

9. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 338, 610 and 324, RSMo.

10. The Settlement Agreement goes into effect upon signature by the Board's Executive Director.

RESPONDENT
JAMES M. KEOWN


James M. Keown

Date:

6/7/9/19

PETITIONER
MISSOURI BOARD OF
PHARMACY

By:

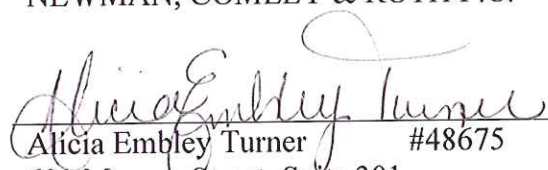

Kimberly Grinston
Executive Director

Date:

7-9-19

NEWMAN, COMLEY & RUTH P.C.

By:


Alicia Embley Turner #48675

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Attorneys for Missouri Board of
Pharmacy

AFFIDAVIT OF VOLUNTARY SURRENDER
OF LICENSE TO PRACTICE PHARMACY

STATE OF Missouri)
) ss.
COUNTY OF Cole)

I, James M. Keown, being first duly sworn upon my oath state:

1. I currently hold a Missouri license to practice pharmacy, numbered 040289.
2. I understand that the Missouri Board of Pharmacy is authorized to pursue disciplinary action upon license number 040289, and that the Missouri Board of Pharmacy is not required to accept a voluntary surrender of this license without a stipulation of facts.
3. It is my intent and desire at this time, after due deliberation, to provide the Missouri Board of Pharmacy with a Settlement Agreement which contains a Joint Stipulation of Facts and Joint Agreed Disciplinary Order.
4. It is my further intent and desire at this time, after due deliberation, to voluntarily surrender my license to practice pharmacy, number 040289, to the Missouri Board of Pharmacy and to provide that Board with any other documents or certificates in my possession evidencing the existence of that license to practice pharmacy.
5. I understand and agree that by voluntary surrender of my license to practice pharmacy, this license becomes as if it were revoked for purposes of regaining licensure in the State of Missouri and such surrender shall be treated as discipline. I further understand and agree that if I apply for licensure in the State of Missouri following the execution of this Affidavit, all facts and information, if any, gathered prior to execution of this affidavit by the Missouri Board of Pharmacy concerning any possible or alleged violations of Chapter 338, RSMo, may be considered in the Board's decision of whether to grant me a new license.

6. I fully understand that, by my execution of this Affidavit, I shall surrender and lose any rights under the law to practice as a pharmacist in the State of Missouri and will not be able to again practice pharmacy in the State of Missouri for seven (7) years and until I reapply for licensure as an original candidate and am accepted by the Missouri Board of Pharmacy.

7. I further understand that my license to practice pharmacy will not be returned to me by the Missouri Board of Pharmacy upon request and that license will cease to exist when it is surrendered.

8. I acknowledge and affirm by this sworn statement that no threats, promises, or assurances of any kind have been made to me regarding the voluntary surrender of my license except as noted above, nor have I been threatened or coerced to so act in any way, but rather I hereby voluntarily surrender my license to practice pharmacy in the State of Missouri by and with this Affidavit.

9. I acknowledge and affirm that I understand that the Board of Pharmacy will maintain this Affidavit of Voluntary Surrender as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

JAMES M. KEOWN

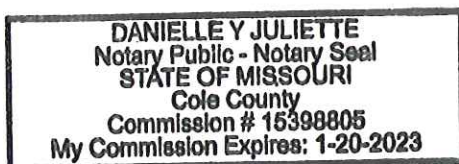
Date:

7/9/19

By:

[Signature]

Subscribed and sworn to before me this 9th day of July, 2019.



[Signature]
Notary Public

My Commission Expires: 01-20-2023

Danielle Y. Juliette
(Print, type or stamp name of notary)